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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. 0825-0166P 09.901,106 07 10.2001 Henrik Garoff 8395 04/01/2003 2292 BIRCH STEWART KOLASCH & BIRCH **EXAMINER PO BOX 747** GUZO, DAVID FALLS CHURCH, VA 22040-0747 ART UNIT PAPER NUMBER 1636

DATE MAILED: 04.01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/901,106	GAROFF ET AL.
	Examiner	Art Unit
	David Guzo	1636
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any - Status		
1) Responsive to communication(s) filed on 13 N	<u>1arch 2003</u> .	
	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4) Claim(s) <u>43,45,51,52 and 63-70</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) <u>43,45,51,52 and 63-70</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement. Application Papers		
9)⊠ The specification is objected to by the Examiner.		
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a)⊠ All b)☐ Some * c)☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No. 07/920,281.		
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) S. Referenced Transport Office S. Referenced Transport Of	5) Notice of Informal Par	PTO-413) Paper No(s) tent Application (PTO-152)
S. Patent and Trademark Office PTO-326 (Rev. 04-01) Office Actio	on Summary	Part of Paper No. 13

Art Unit: 1636

Detailed Action

This is a Supplemental Action necessitated by entry of the amendment that was originally filed 12/19/02 but never entered into the file. The amendment reintroduces claims 64-70, which were inadvertently cancelled (as claims 54-60) by applicants in the paper filed 11/25/02.

The indicated allowability of claims 54-60 (now claims 64-70) is withdrawn in view of the newly applied reference to Johnston et al. (U.S. Patent 5,792,462).

Rejections based on the newly cited reference follow.

The new matter and 112, 2nd paragraph rejections made in the previous Office Action are withdrawn because further examination of the application indicates that the specific limitations objected to as new matter are indeed present in a preliminary amendment filed with the application on 7/10/01. Additionally, these limitations were first presented in claims filed by preliminary amendment in the parent application (09/371,510, filed 8/10/99). However, benefit for these embodiments is granted back only to the filing date of the 09/371,510 application as these limitations do not appear in applications filed prior to the 09/371,510 application.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Art Unit: 1636

The oath or declaration is defective because: Applicants added claims which represent new matter to the 09/371,510 application in a preliminary amendment filed 8/10/99. This new matter is also being claimed in the instant application, which applicants assert is a continuation of the 09/371,510 parent. Therefore a supplemental C-I-P Oath or Declaration is required under 37 CFR 1.67 because the oath filed with the 09/371,510 application and the instant application (a copy of the oath from the 07/920,281 application, dated 1/7/92) does not indicate that applicants have reviewed and understand the contents of the specification as amended to include the new matter. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 45, 51-52 and 63-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnston et al.

Both applicants and Johnston et al. (previously cited, U.S. Patent 5,792,462, issued 8/11/98, filed 5/23/95, see whole document, particularly Claims 1-27) recite the same helper cells comprising the same alphavirus replicons and helper RNAs, the same methods for making infectious replication defective alphavirus particles and infectious alphavirus particles. Johnston et al. therefore teaches the claimed invention. It is noted that this reference is applicable under 35 USC 102(e) because applicants are

Art Unit: 1636

granted benefit for the claimed subject matter only back to the filing date of the parent application 09/371,510, filed 8/10/99.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 43, 45, 51-52 and 63-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnston et al.

Johnston et al. is cited as in the above 35 USC 102(e) rejection. As noted in the above 102(e) rejection, Johnston et al. teaches the claimed helper cells, alphavirus replicons, methods of making infectious replication defective alphavirus particles and alphavirus particles made by the recited method.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The following is not described in the specification: The subject matter of claims 43, 45, 51-52 and 63-70 regarding helper cells, alphavirus replicons, the limitations of more than one helper RNAs, the characteristics of the helper RNAs and the properties of the replicons.

No Claims are allowed.

Art Unit: 1636

Page 5

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo March 31, 2003

> DAVID GUZO RIMARY EXAMINER